

LISTING OF CLAIMS

The following listing of claims replaces all prior versions and listings of claims in the present application:

Claim 1 (currently amended): A throat, mouth and/or gum sprayable topical pharmaceutical preparation in the form of an aqueous solution comprising:

a non-steroidal anti-inflammatory drug (NSAID) also having analgesic activity;

a biologically compatible ~~buffer~~ base consisting essentially of an organic amine selected from at least one of D-glucamine, meglumine, trometamol (~~tris buffer~~) and a mixture thereof, in a quantity suitable for buffering the pH of the preparation within the range specified below;

a pH within a range from 6.5 to ~~[[8.0]]~~ 6.9; and

pharmaceutical grade water;

wherein the NSAID is flurbiprofen in a quantity of from ~~[[1.5]]~~ 2.0 mg/ml to ~~[[8.0]]~~ 4.0 mg/ml.

Claim 2 (withdrawn): Use of a sprayable pharmaceutical preparation in the manufacture of an anti-inflammatory agent for treating the mouth, throat and/or gums, wherein the pharmaceutical preparation is in the form of an aqueous solution comprising:

a non-steroidal anti-inflammatory drug (NSAID) also having analgesic activity;

a biologically compatible buffering organic amine provided with a free or monosubstituted amino group or a mixture thereof, in a quantity suitable for buffering the pH of the preparation within the range specified below;

a pH within a range from 6.5 to 8.0; and

pharmaceutical grade water;

wherein the NSAID is flurbiprofen and the biologically compatible buffering organic amine is D-glucamine, meglumine, trometamol (tris buffer) or a mixture thereof.

Claim 3 (previously presented): A pharmaceutical preparation according to claim 1, wherein the flurbiprofen is in the form of a racemate or one of its enantiomers selected from R-(-) flurbiprofen and S-(+) flurbiprofen.

Claim 4 (cancelled).

Claim 5 (cancelled).

Claim 6 (currently amended): A pharmaceutical preparation according to claim 1, wherein D-glucamine is present in a quantity of from ~~about~~ 0.35 mg/ml to ~~about~~ 1.12 mg/ml; and/or meglumine is present in a quantity of from ~~about~~ 0.40 mg/ml to ~~about~~ 2.4 mg/ml; ~~and/or trometamol is present in a quantity of from about 0.10 mg/ml to about 0.75 mg/ml.~~

Claim 7 (cancelled).

Claim 8 (currently amended): A pharmaceutical preparation according to claim 1, further comprising:

a mild disinfectant; and/or
one or more preservatives; and
wherein:

the mild disinfectant comprises at least one of (i) cetylpyridinium chloride, present, if at all, in a quantity of from ~~about~~ 1.0 mg/ml to ~~about~~ 6.0 mg/ml, and (ii) glycyrrhizic acid or a salt thereof, present, if at all, in a quantity of from ~~about~~ 0.8 mg/ml to ~~about~~ 1.2 mg/ml; and

the preservative comprises at least one of (i) methyl p-hydroxybenzoate, present, if at all, in a quantity of from ~~about~~ 0.25 mg/ml to ~~about~~ 1.15 mg/ml, (ii) propyl p-hydroxybenzoate, present, if at all, in a quantity of from ~~about~~ 0.03 mg/ml to ~~about~~ 0.15 mg/ml, (iii) disodium calcium edetate, present, if at all, in a quantity of from ~~about~~ 0.1 mg/ml to ~~about~~ 1.0 mg/ml, and (iv) sodium benzoate, in a quantity of from ~~about~~ 0.2 mg/ml to ~~about~~ 5.0 mg/ml.

Claim 9 (previously presented): A pharmaceutical preparation according to claim 1, further comprising at least one further ingredient selected from the group consisting of a viscosity agent, a sweetening agent, a fluidising agent, a thickening agent, a colouring agent and a natural essence of flavouring agent.

Claim 10 (currently amended): A pharmaceutical preparation according to claim 9, wherein the further ingredient is selected from the group consisting of ~~at least one of~~ glycerol, sorbitol, xylitol, ethyl alcohol, castor oil 40 polyethoxylate, saccharin sodium, acesulfame potassium, mint essence, natural mint flavour, natural peach flavour and patent blue V-E131, E-124.

Claim 11 (previously presented): A pharmaceutical preparation according to claim 1, further comprising xylitol.

Claim 12 (currently amended): A pharmaceutical preparation according to claim 1, wherein the preparation is in the form of a mouthwash for spraying, with a dispensed volume for each unit dose of from ~~about~~ 100 microlitres (0.1 ml) to ~~about~~ 300 microlitres (0.3 ml).

Claim 13 (cancelled).

Claim 14 (previously presented): A packaged pharmaceutical preparation according to claim 1, wherein the preparation is equipped with a dosing pump.

Claim 15 (withdrawn): A process for the production of the pharmaceutical preparation defined in claim 1, comprising:

- (i) dissolving preservative(s) in a solution;
- (ii) dissolving the selected NSAID in water or a water/ethyl alcohol mixture and buffering with the organic amine to the specified pH value;
- (iii) adding any auxiliary ingredients to the solution of step (i), and mixing the solution of step (i) with the solution of NSAID and organic amine from step (ii);

(iv) making up to volume (or weight) with water, if necessary, and adjusting the pH to the prescribed value with addition of organic amine.

Claim 16 (currently amended): A pharmaceutical preparation according to claim 1, wherein the flurbiprofen is present in a quantity of ~~about~~ 2.5 mg/ml.

Claim 17 (currently amended): A pharmaceutical preparation according to claim 12, wherein the dispensed volume for each unit dose is ~~about~~ 200 microlitres (0.2 ml).

Claim 18 (withdrawn): The use according to claim 2, wherein the flurbiprofen is in the form of a racemate or one of its enantiomers selected from R-(-) flurbiprofen and S-(+) flurbiprofen.

Claim 19 (withdrawn): The use according to claim 2, wherein the flurbiprofen is present in a quantity of from about 1.5 mg/ml to about 8.0 mg/ml.

Claim 20 (withdrawn): The use according to claim 2, wherein the flurbiprofen is present in a quantity of about 2.5 mg/ml.

Claim 21 (withdrawn): The use according to claim 2, wherein the pH of the solution is between about 7.0 and about 7.5.

Claim 22 (withdrawn): The use according to claim 2, wherein D-glucamine is present in a quantity of from about 0.35 mg/ml to about 1.12 mg/ml; meglumine is present in a quantity of from about 0.40 mg/ml to about 2.4 mg/ml; and/or trometamol is present in a quantity of from about 0.10 mg/ml to about 0.75 mg/ml.

Claim 23 (withdrawn): The use according to claim 2, wherein the buffer is present in a quantity suitable for buffering the pH of the solution within the range of between about 7.0 and about 7.5.

Claim 24 (withdrawn): The use according to claim 2, wherein the pharmaceutical preparation further comprises:

a mild disinfectant; and/or
one or more preservatives; and
wherein:

the mild disinfectant comprises at least one of (i) cetylpyridinium chloride, optionally in a quantity of from about 1.0 mg/ml to about 6.0 mg/ml, optimally about 5.0 mg/ml, and (ii) glycyrrhizic acid or a salt thereof, optionally in a quantity of from about 0.8 mg/ml to about 1.2 mg/ml, optimally about 1.0 mg/ml; and

the preservative comprises at least one of (i) methyl p-hydroxybenzoate, optionally in a quantity of from about 0.25 mg/ml to about 1.15 mg/ml, (ii) propyl p-hydroxybenzoate, optionally in a quantity of from about 0.03 mg/ml to about 0.15 mg/ml, (iii) disodium calcium edetate, optionally in a quantity of from about 0.1 mg/ml to about 1.0 mg/ml, and (iv) sodium benzoate, optionally in a quantity of from about 0.2 mg/ml to about 5.0 mg/ml.

Claim 25 (withdrawn): The use according to claim 2, wherein the pharmaceutical preparation further comprises at least one further ingredient selected from the group consisting of a viscosity agent, a sweetening agent, a fluidising agent, a thickening agent, a colouring agent and a natural essence of flavouring agent.

Claim 26 (withdrawn): The use according to claim 25, wherein the further ingredient is selected from the group consisting of at least one of glycerol, sorbitol, xylitol, ethyl alcohol, castor oil 40 polyethoxylate, saccharin sodium, acesulfame potassium, mint essence, natural mint flavour, natural peach flavour and patent blue V-E131, E-124.

Claim 27 (withdrawn): The use according to claim 2, wherein the pharmaceutical preparation further comprises xylitol.

Claim 28 (withdrawn): The use according to claim 2, wherein the preparation is in the form of a mouthwash for spraying, preferably with a dispensed volume for each unit dose of from about 100 microlitres (0.1 ml) to about 300 microlitres (0.3 ml).

This paper is filed in response to the Office Action mailed on 12 May 2010, making non-final rejections of the claims.

Claim 29 (withdrawn): The use according to claim 28, wherein the dispensed volume for each unit dose is about 200 microlitres (0.2 ml).

Claim 30 (withdrawn): The use according to claim 2, wherein the buffer is D-glucamine, meglumine, or a mixture thereof.

Claim 31 (withdrawn): The use according to claim 2, wherein the pharmaceutical preparation is supplied with a dosing pump.

Claim 32 (cancelled).